

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

CIVIL ACTION NO. 13-11640-RWZ

BRIGHAM AND WOMEN'S HOSPITAL, INC.,
and INVESTORS BIO-TECH, L.P.

v.

PERRIGO COMPANY and L. PERRIGO COMPANY

MEMORANDUM OF DECISION

January 28, 2015

ZOBEL, D.J.

Plaintiffs Brigham and Women's Hospital, Inc., and Investors Bio-Tech, L.P. (collectively, "BWH") seek damages from defendants Perrigo Company and L. Perrigo Company (collectively, "Perrigo") for alleged patent infringement under 35 U.S.C. §§ 271(a)-(c). BWH contends that the asserted patent, U.S. Patent No. 5,229,137 (the '137 patent"), covers the drug sold by its licensees under the brand name Pepcid® Complete®. Perrigo has sold a generic form of that drug since 2008.

Perrigo moves for judgment on the pleadings and for summary judgment, contending that BWH's claims are barred by laches and, in any event, are moot because BWH failed to ensure that Pepcid® Complete® was marked with the patent number. See Docket ## 27, 46. BWH moves to amend its complaint to plead around the alleged failure to mark. See Docket # 54. For the reasons that follow, Perrigo's

motions are denied, and BWH's motion to amend is allowed.

I. Background

The '137 patent covers both a composition to treat episodic heartburn and a method of using that composition. The inventions claimed in the patent were purportedly developed by scientists at plaintiff Brigham and Women's Hospital, which owns the patent. Plaintiff Investors Bio-Tech, L.P., was, at all relevant times, the exclusive licensee of the patent.

In the late 1990s, a group of BWH's licensees filed a New Drug Application ("NDA") with the U.S. Food and Drug Administration ("FDA") for what is now known as Pepcid® Complete®. With their NDA, BWH's licensees told FDA that three patents, including the '137 patent, covered the drug. FDA added these patents to its Orange Book, which lists approved drugs and the patents that cover them. The FDA approved the Pepcid® Complete® NDA in 2000, and BWH's licensees have sold the drug ever since.

In 2004, Perrigo submitted an Abbreviated New Drug Application ("ANDA") to the FDA seeking to market a generic version of Pepcid® Complete®. With its ANDA, Perrigo submitted a certification alleging that each of the patents listed in the Orange Book for Pepcid® Complete® was invalid, unenforceable, or not infringed by its proposed generic product—a so-called Paragraph IV certification, named after the section of the law authorizing it. See 21 U.S.C. § 355(j)(2)(A)(vii)(IV). As required by the Hatch-Waxman Act, 21 U.S.C. § 355(j)(2)(B), Perrigo sent plaintiff Brigham and Women's Hospital—the owner of the Orange Book-listed '137 patent—notice of its

Paragraph IV certification. Perrigo sent similar notifications to the owners of the other two Orange Book-listed patents.

The Hatch-Waxman Act makes a Paragraph IV certification an artificial act of patent infringement, creating subject matter jurisdiction for a patent infringement suit in federal courts. 35 U.S.C. § 271(e)(2); Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 678 (1990) (“That is what is achieved by § 271(e)(2)—the creation of a highly artificial act of infringement that consists of submitting an ANDA or a paper NDA containing the fourth type of certification . . .”). In response to Perrigo’s Paragraph IV certification, the owners and licensees of one of the other two Orange Book-listed patents timely sued Perrigo for patent infringement in the United States District Court for the Southern District of New York. BWH, however, did not react to the Paragraph IV certification for the ’137 patent.

The Southern District of New York invalidated the only Pepcid® Complete® patent before it, and the Federal Circuit affirmed in 2008. Perrigo then launched its generic version of Pepcid® Complete®, and it has been making and selling the product ever since. On July 9, 2013—over a year after the patent expired—BWH sued Perrigo for infringement of the ’137 patent.¹

II. Perrigo’s Motion for Judgment on the Pleadings

First, Perrigo moves for judgment on the pleadings under Federal Rule of Civil Procedure 12(c). Although this is a patent case where the law of the Federal Circuit governs substantive matters, First Circuit law governs the standard of review. Imation

¹ The complaint also named CVS Care Corp., but plaintiff later dismissed these claims.

Corp. v. Koninklijke Philips Electronics N.V., 586 F.3d 980, 984 (Fed. Cir. 2009). In resolving this motion, the court considers only the pleadings, materials incorporated by reference in the pleadings, and facts susceptible to judicial notice. See R.G. Fin. Corp. v. Vergara-Nunez, 446 F.3d 178, 182 (1st Cir. 2006). All factual allegations of the non-moving party are taken as true, and all inferences of fact are drawn in the non-moving party's favor. Id.

Perrigo's motion contends that the equitable defense of laches bars BWH's claims. There are two factual elements to a laches defense: that "the plaintiff delayed filing suit for an unreasonable and inexcusable length of time from the time the plaintiff knew or reasonably should have known of its claim against the defendant," and that "the delay operated to the prejudice or injury of the defendant." A.C. Aukerman Co. v. R.L. Chaides Const. Co., 960 F.2d 1020, 1032 (Fed. Cir. 1992). "The underlying critical factors of laches are presumed upon proof that the patentee delayed filing suit for more than six years after actual or constructive knowledge of the defendant's alleged infringing activity." Id. at 1035-36. This presumption, however, "completely vanishes upon the introduction of evidence sufficient to support a finding of the nonexistence of the presumed fact." Id. at 1037. Because "[t]he facts evidencing unreasonableness of the delay, lack of excuse, and material prejudice to the defendant, are seldom set forth in the complaint," it is generally inappropriate to grant a motion for judgment on the pleadings "based solely on presumptions" of laches. Advanced Cardiovascular Sys., Inc. v. Scimed Life Sys., Inc., 988 F.2d 1157, 1161 (Fed. Cir. 1993).

Perrigo's motion, however, asks the court to do just that. Because BWH filed this suit more than six years after it found out about Perrigo's allegedly infringing activity, Perrigo contends that laches is presumed. However, BWH points out that this case is based not on Perrigo's ANDA activities but on its infringement activities proscribed by 35 U.S.C. § 271(a), which may have arisen more recently. Similarly, BWH contends that Perrigo has suffered no economic prejudice from its delay in bringing suit, which Perrigo contests. Docket # 40 at 19. Both of these points, as well as others raised in the parties' submissions, involve factual disputes about the elements of Perrigo's laches defense that cannot be resolved at this stage. The motion to dismiss is denied.

III. BWH's Motion to Amend the Complaint

BWH moves to amend its complaint to allege only infringement of the '137 patent's method claims rather than both its method and composition claims. This is presumably to avoid the failure to mark defense that Perrigo raises in its motion for summary judgment (Docket # 46).

Leave to amend a complaint "shall be freely given when justice so requires." Fed. R. Civ. P. 15(a). Leave ought to be given unless there is a good reason to deny it. See Foman v. Davis, 371 U.S. 178, 182 (1962). Reasons to deny leave to amend include, among others, bad faith or dilatory motive on the part of the movant, undue prejudice to the opposing party by virtue of allowance of the amendment, and futility of the amendment. Id. First Circuit law governs whether to allow leave to amend. See Chi. Bd. Options Exch., Inc. v. Int'l Sec. Exch., LLC, 677 F.3d 1361, 1374 (Fed. Cir.

2012).

A. Bad Faith or Dilatory Motive

Plaintiffs have several valid reasons to seek to amend the complaint in good faith. First, the proposed amendment only narrows the scope of BWH's asserted claims. Eliminating issues will in no way delay this case's resolution. Although the proposed amendment is a transparent attempt to plead around a possible defense, plaintiffs are entitled to assert only a subset of their possible claims if they so choose. If pleading to avoid defenses constituted bad faith, few motions to amend would be granted.

B. Futility

Amendment is futile and should be denied if the amended complaint is still insufficient to state a viable claim. See Adorno v. Crowley Towing & Transp. Co., 443 F.3d 122, 126 (1st Cir. 2006). The standard for legal sufficiency is typically the same standard that governs motions to dismiss under Federal Rule of Civil Procedure 12(b)(6). Id. Although a pending motion for summary judgment, as here, may require a plaintiff to make a greater showing for leave to amend, courts typically raise the standard only after discovery is substantially complete. Cf. Hatch v. Dep't for Children, Youth & Their Families, 274 F.3d 12, 19 (1st Cir. 2001) (applying higher "substantial evidence" standard after the party seeking to amend "had the full run of discovery"). Because no discovery has occurred in this case, the amended complaint must meet only the standard Rule 12(b)(6) threshold.

If taken in the light most favorable to the plaintiffs, the proposed amended

complaint states a claim upon which relief could be granted. Perrigo contends that BWH's failure to mark its product in compliance with 35 U.S.C. § 287(a) defeats its claims, even if BWH only asserts the method claims of the '137 patent in this case. However, in Crown Packaging Technology, Inc. v. Rexam Beverage Can Co., 559 F.3d 1308, 1317 (Fed. Cir. 2009), the Federal Circuit held that "the marking requirement . . . does not apply when only method claims are asserted." Id. at 1310. By amending its complaint to clarify that it is only asserting the method claims of the '137 patent, BWH avoids the marking requirement.

Defendants' other allegations of futility are without merit. That Claim 20, a composition claim, was originally asserted has no bearing on whether Claim 20 is being asserted in the amended complaint. The amended complaint "supersedes the original complaint, and facts that are neither repeated nor otherwise incorporated into the amended complaint no longer bind the pleader." Intergent, N.V. v. Grina, 344 F.3d 134, 144-45 (1st Cir. 2003).

C. Equity

Finally, amendment should be granted when equity so requires. Had the defendants asserted this defense in their answer, plaintiffs would have had the opportunity to amend as a matter of course. No discovery has occurred in this case, and the proposed amended complaint sets forth largely identical legal and factual claims. Indeed, it narrows the scope of the case and will reduce the burden of discovery on both parties. The amendment therefore poses little threat of prejudice.

IV. Perrigo's Motion for Summary Judgment

Plaintiffs' complaint, as amended, now maintains only the method claims of the '137 patent. InterGen N.V., 344 F.3d at 145. Section 287(a)'s marking requirement therefore no longer applies. See Crown Packaging Tech., Inc. v. Rexam Beverage Can Co., 559 F.3d 1308, 1317 (Fed. Cir. 2009) ("Because [plaintiff] asserted only the method claims of the . . . patent, the marking requirement of 35 U.S.C. § 287(a) does not apply."). Defendants' motion for summary judgment is therefore denied.

V. Conclusion

Defendants' motion for judgment on the pleadings (Docket # 27) is DENIED, plaintiffs' motion to amend the complaint is ALLOWED (Docket # 54), and defendants' motion for summary judgment (Docket # 46) is DENIED.

January 28, 2015

DATE

/s/Rya W. Zobel

RYA W. ZOBEL
UNITED STATES DISTRICT JUDGE